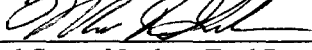
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Approved: M. D. Gardner 
Manager, National Spent Nuclear Fuel Program

Date: 10/12/2004

I. PURPOSE AND SCOPE

This procedure establishes the process used by the National Spent Nuclear Fuel Program (NSNFP) for determining quality program applicability and integrating the determinations with the planned *technical work* (see glossary). Methods are established by this procedure to ensure that the technical work is accomplished under suitably controlled conditions.

The work associated with NSNFP Quality Assurance Staff (QAS) functions, PSO Quality Engineering (QE) functions, records management activities, document control coordinator functions, and the training coordinator functions are already deemed *quality affecting* (see glossary) and are not subject to this procedure. In all cases, NSNFP Quality Assurance (QA) Program implementing procedures are maintained to control these functions or activities.

Program execution functions, including program management activities related to budgeting and scheduling, master logic scheduling, and stakeholder interactions, are deemed nonquality affecting and are not subject to this procedure.

II. SUMMARY

NSNFP work planning is documented using criteria prescribed by this procedure. This produces a documented determination of quality program applicability that is integrated with the planned approach to performing the technical work (path forward). The documentation is titled, "NSNFP Planning/QA Program Applicability Evaluations." The technical work *activities* (see glossary) are grouped into logical segments for evaluation.

Only the technical work activities evaluated in accordance with this procedure are allowed to proceed.

The procedure also provides for documentation of the technical work as it is completed.

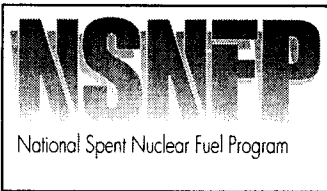
The approved NSNFP Planning/QA Program Applicability Evaluations provide a mechanism to communicate the required QA program controls associated with the technical work to be performed.

III. PROCEDURE

A. Initiating NSNFP Planning/QA Program Applicability Evaluations and Changes

PSO Technical 1. Assign PSO technical staff to prepare NSNFP Planning/QA Applicability
Lead Evaluations and changes when:

- a. New technical work scope is added.

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PSO Technical
Lead

- b. A revision to DOE/RW-0333P, *Quality Assurance Requirements and Description* (QARD), impacts the current evaluation as determined by analysis conducted by the NSNFP Quality Assurance Staff Manager (QASM).
- c. A previously unknown portion of the planned approach to performing the technical work (path forward) has been determined.
- d. A Planning/QA Program Applicability Evaluation omission or error is identified.
- e. Updates to the performance history are requested.
- f. The technical work is completed allowing closure of the evaluation.

Note: With the exception of the above conditions, NSNFP Planning/QA Program Applicability Evaluations may otherwise continue year after year unmodified.

B. Determining Quality Assurance Program Applicability

PSO Technical
Staff

- 1. Based on work descriptions and information contained in budget documentation, master logic schedules, life cycle planning documents, or other documents, provide a description of the deliverables associated with the technical work activities.
- 2. Using the format and criteria in this procedure's attachments, evaluate the technical work and record the results using NSNFP Planning/QA Program Applicability Evaluations.
- 3. Provide draft NSNFP Planning/QA Program Applicability Evaluations to a PSO QE for input.

PSO QE
Personnel

- 4. Review the draft NSNFP Planning/QA Program Applicability Evaluations prepared by the NSNFP PSO Staff to ensure consistency with the format and criteria of Attachments A through D and the current NSNFP QARD Requirements Matrix.
 - a. When activities require a new or revised procedure, note the condition in the special instruction section of Attachment A.
- 5. Compare the performing organizations identified as *government sector supplier* (see glossary) and the anticipated work scope with the acceptance basis and restrictions for suppliers on the NSNFP qualified supplier list, the OCRWM-approved supplier list, or accepted DOE SNF Site Implementing Matrices.



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- PSO QE
Personnel
6. Provide input regarding the supplier QA program acceptance status and further supplier evaluation needs for the identified government sector supplier organizations.
 7. Provide input regarding the supplier QA program scope for the work identified for performance by private sector suppliers.

C. Completing NSNFP Planning/QA Program Applicability Evaluation Documentation


- PSO Technical
Staff
1. Begin the formal review cycle according to NSNFP Procedure 6.01.
 2. Distribute the approved NSNFP Planning/QA Program Applicability Evaluation to the affected NSNFP PSO personnel, PSO QE, and NSNFP QAS Organization Manager according to NSNFP Procedure 6.03.
 3. Submit the approved NSNFP Planning/QA Program Applicability Evaluation for record retention in accordance with NSNFP Procedure 17.01.

D. Use of Approved NSNFP Planning/QA Program Applicability Evaluations

- PSO Technical
Staff
1. Guided by approved NSNFP Planning/QA Program Applicability Evaluations:
 - a. Develop Task Management Agreements for government sector suppliers in accordance with NSNFP Procedure 4.02.
 - b. Perform needed coordination with NSNFP QAS personnel to support QA program acceptance for government sector suppliers.
 - c. Develop requisitions for private sector suppliers in accordance with NSNFP Procedure 4.01 and NSNFP approved procurement service procedures.
 - d. Perform needed coordination with the NSNFP-approved M&O Contractor Procurement Service to support QA program review and acceptance activities for private sector suppliers.

E. Performance History and Closure of NSNFP Planning/QA Program Applicability Evaluations

- PSO Technical
Staff
1. Upon request from the NSNFP PSO Manager at any stage of progress, update the performance history section of the NSNFP Planning/QA Program Applicability Evaluation and process the updated NSNFP Planning/QA Program Applicability Evaluations as a change.

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|---------------------|----|---|
| PSO Technical Staff | 2. | At the completion of technical work, complete the performance history section and submit the NSNFP Planning/QA Program Applicability Evaluation to the NSNFP PSO Manager and PSO QE for closeout. |
| PSO QE Personnel | 3. | Approve the closeout of the NSNFP Planning/QA Program Applicability Evaluation based on the absence of open Deficiency Reports or Corrective Action Requests applicable to the technical work. |
| PSO Manager | 4. | Approve the closeout of the NSNFP Planning/QA Program Applicability Evaluation based on review of the list of deliverables against the deliverables planned within the control account work breakdown structure item. |
| PSO Technical Staff | 5. | Upon receiving closeout approval, submit the closed NSNFP Planning/QA Program Applicability Evaluation for record retention in accordance with NSNFP Procedure 17.01. |

IV. REFERENCES

None.

V. DEFINITIONS

Terms appearing in italics followed by the notation "see glossary" are defined in the NSNFP Documents Manual Introduction and Glossary.

VI. ATTACHMENTS

Attachment A, NSNFP Planning/QA Program Applicability Evaluation Format Attachment B, NSNFP Planning/QA Program Applicability Evaluation Format (Flowdown to suppliers)

Attachment C, Criteria for Determining QA Program Applicability

Attachment D, Criteria for Applying Quality Assurance Controls

VII. QUALITY RECORDS

The following quality records generated as a result of this procedure require retention in accordance with the identified classification and NSNFP Procedure 17.01.

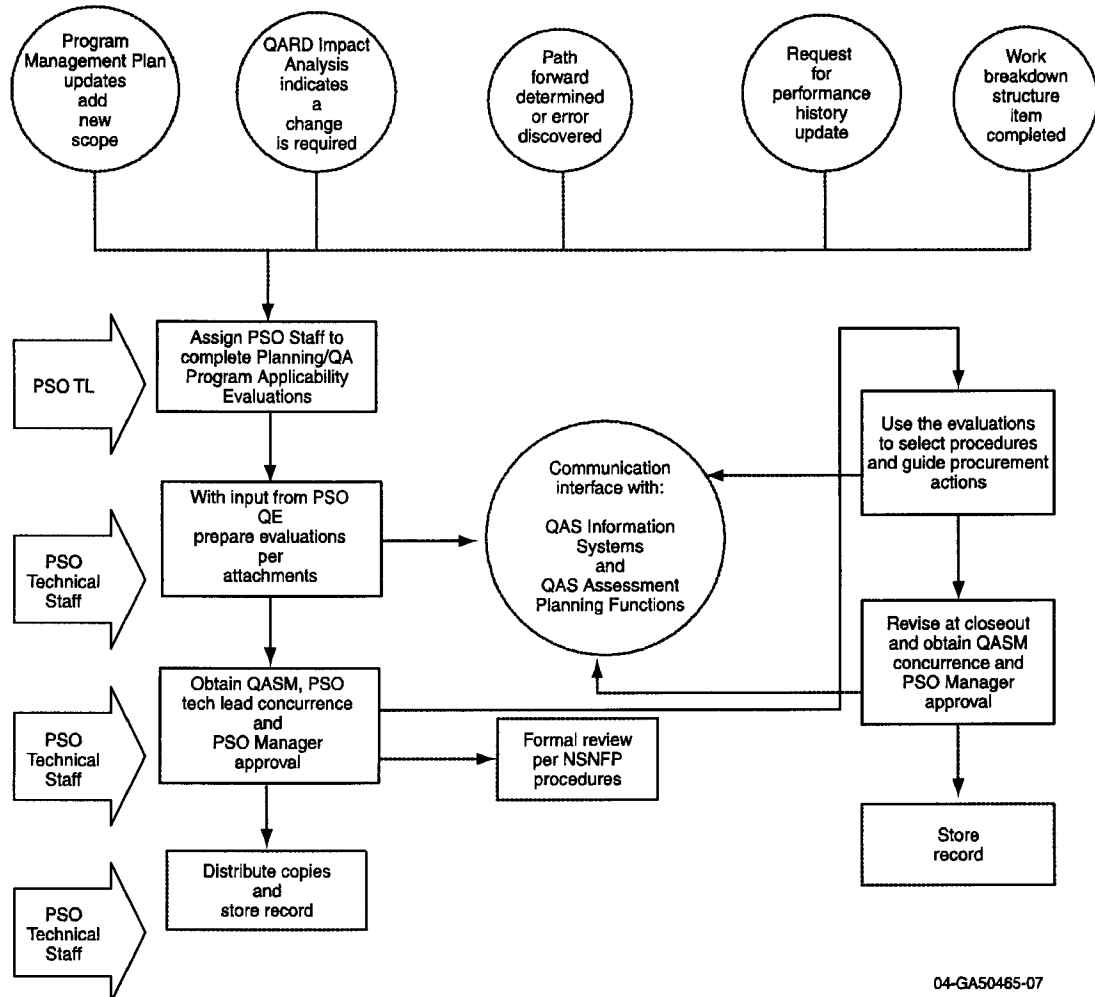
Lifetime

- A. Approved NSNFP Planning/QA Applicability Evaluations and changes thereto.
- B. Closed NSNFP Planning/QA Applicability Evaluations

Nonpermanent

None.

VIII. PROCEDURE FLOW DIAGRAM





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Attachment A

NSNFP Planning/QA Program Applicability Evaluation (PAE) Format

Control Account Number (WBS number): _____ Page ____ of ____ NSNFP DAR No. _____
Control Account Title _____ PAE Revision Number 0,1, 2, 3, etc. _____
Work Breakdown Structure Item Title _____ Date of preparation for this evaluation _____

Prepared by: _____ / _____ / _____
Printed Name Signature Date

NSNFP Planning/QA Program Applicability Evaluation Approval

The evaluated work activities may be performed as planned.

NSNFP PSO

Technical Lead _____ / _____ / _____
Printed Name Signature Date

NSNFP QASM _____ / _____ / _____
Printed Name Signature Date

NSNFP PSO Manager _____ / _____ / _____
Printed Name Signature Date

Description of Technical Work Deliverables

For the technical work of the subject control account work breakdown structure item, provide a description of the deliverables. Discuss in general the scientific approach or technical methods to be used to collect, analyze, or study the results of the technical work and the associated prerequisites, special controls, environmental conditions, processes, or skills.

End Use of the Deliverables

Discuss the end use including the influence of the deliverables on the Repository Safety Analysis, Repository Design, SNF conditioning or characterization, or SNF packaging, handling, transportation, and waste acceptance.

Note: Certain technical work activities are subject to decisions made during scoping efforts and, as a result, may not be pursued ultimately. For these and other research and development efforts indicate the point at which the NSNFP QA Program controls apply should the work proceed beyond scoping.

Amplifying Information

Provide additional information that explains the QA applicability determination. When engineering judgment is used to graduate the application of the NSNFP QA Program, provide technically defensible basis.

NSNFP Internal Work Scope

Describe the technical work scope to be performed directly by the NSNFP Program Support Organization. Indicate if staff augmentation will be used and the source, if known. Identify appropriate implementing document and guidance documents: NSNFP Documents Manual, OCRWM technical guidance documents, NSNFP developed guidance, etc. Identify computer software to be used. Identify other implementing procedures or documents to be developed, if needed.

Identify items, test specimens, hardware, and software to be purchased directly by NSNFP from the private sector for use by NSNFP or a NSNFP supplier.



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Government Sector Suppliers

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Indicate if government sector performing organizations will be used and describe the work to be accomplished by the performing organization (include procurement services for NSNFP purchases from private sector firms). If known, identify field and laboratory testing equipment, computer software to be used, and the primary facilities involved. Include Attachment B as applicable.

Private Sector Suppliers

Indicate if the services of private sector firms will be procured by NSNFP. Indicate the anticipated division of work among private sector firms. Designating the firms as Firm A, B, C, etc., describe the work to be accomplished by each firm. Note: A final determination regarding the number of firms and specific firms used occurs during the procurement process. Include Attachment B as applicable.

Administrative Processes used to control work

Using Attachment D as a guide to establish the degree of work control to be applied, generally describe the work controls to be used, such as:

- NSNFP procedures will be used for internal work and external interfaces
- NSNFP Task Management Agreements will be used to interface with DOE SNF sites and other government agencies (Government Sector Suppliers to NSNFP)
- The procedures of the NSNFP-approved procurement services (for private sector procurements) will be used to interface with private sector firms.

QA Oversight and Verifications to be used

Using Attachment D as a guide to establish the degree of QA oversight and verification to be applied, describe the QA oversight and verifications to be used, such as:

- NSNFP PSO will perform technical reviews, checker functions, and backup calculations per NSNFP procedures.
- PSO QE will perform document reviews as described by NSNFP procedures.
- PSO QE will provide the quality engineering function for procurements from the private sector
- As applicable, NSNFP QAS will provide assessments for qualified supplier status for the following DOE SNF sites and other government agencies (list the SNF sites and other government agencies requiring initial or expanded supplier qualification to perform NSNFP sponsored work).
- NSNFP QAS will periodically audit the procurement service as a supplier to the NSNFP and observe selected audits of the private sector firms performed by the procurement service.
- NSNFP QAS will assess QA program implementation for the work of this control account on a periodic basis.

Special Instructions

Identify activities that require a new or revised NSNFP procedure as a prerequisite condition that must be satisfied prior to beginning the work. Indicate the nature of the procedure needed and related QARD sections.

Describe hold points necessitated by the existence of an indeterminate path forward and indicate that work must not proceed past that planning hold point.

Provide other special instructions to augment the evaluation when necessary.



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Attachment A

NSNFP Planning/QA Program Applicability Evaluation Format

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Performance History

Date Prepared _____

Note: Update the performance history section of an approved NSNFP Planning/QA Program Applicability Evaluation as applicable during the preparation of the initial evaluations involving activities completed prior to the release of Revision 4 of the NSNFP Procedure 2.05.

Record the document number, title, and storage location (building and room) for each revision of each task deliverable.

Record the document number, title, and storage location (building and room) for each revision of applicable scientific investigation plans, test plans, NSNFP technical documents providing requirements, and NSNFP technical documents providing guidance.

Record the document number, title, and storage location (building and room) for each revision of applicable Task Management Agreements (or as previously termed, "Statements of Work").

Record the assessment number, title, and storage location (building and room) of NSNFP QA Assessments specific to the task or subtasks.

NSNFP QA Applicability Evaluation Closeout (at completion of the Technical Work)


Based on review of the recorded performance history and the QA assessment closure status, the technical work described by this evaluation is closed.

NSNFP QASM Approval

_____/_____
Printed Name Signature

NSNFP PSO Manager Approval

_____/_____
Printed Name Signature

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Attachment B

NSNFP Planning/QA Program Applicability Evaluation (Flowdown to Suppliers)

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Control Account Number (WBS #) Control Account Title _____ QARD Revision Level Used at Time of Evaluation _____	Work Breakdown Structure Item _____ Date of Preparation _____
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Place an X in the block corresponding to the QARD section and the performing organization to indicate the QARD sections applicable to that organization's planned scope of work. Where QARD subsections are not applicable, note the exception. If the entire QARD section is not applicable to the planned work scope for a particular performing organization, enter Not Applicable (NA). If certain aspects of the Planning/QA Program Applicability Evaluation cannot be sufficiently defined to make a determination, enter To Be Determined (TBD) in the appropriate blocks. When a TBD is entered, describe in the Planning/QA Program Applicability Evaluation special instructions section the point at which work may not proceed without revision to the plan.

The basis for a NSNFP supplier QA program may be other than, but consistent with, the QARD for the work scope established by NSNFP.

Performing Organization Titles

Note: When referring to a private sector entity as the planned performing organization, use the term "private sector firm A, B, C, etc." instead of a company name.

QARD Section (Examples—not all sections shown)	INEEL M&O Contractor Procurement Service (Example)	Government Sector Supplier (Example)	Private Sector Firm A (Example)	Private Sector Firm B (Example)	Private Sector Firm C (Example)
Section 1 Organization	X Except Section 1.3	X Except Section 1.3	X Except Section 1.3	X Except Section 1.3	X Except Section 1.3
Section 2 Quality Assurance Program	X	X	X -Except 2.2.7	X -Except 2.2.7	X -Except 2.2.7
Section 4 Procurement Document Control	X	NA	X	X	X
Section 5 Implementing Documents	X	X	X	X	X
Section 6 Document Control	X	X	X	X	X
Section 7 Control of Purchased Items and Services	X	NA	X	X	X
Section 16 Corrective Action	X	X	X	X	X
Supplement I Software	NA	X	X	X	X
Supplement III Scientific Investigation	NA	NA	X	X	X



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Attachment C

Criteria for Determining QA Program Applicability

The NSNFP develops and reviews QA Applicability Evaluations using the following guidelines.


The QA program shall be applied to:

All structures, systems, and components (SSCs) important to safety or waste isolation
Design and characterization of barriers important to waste isolation

Activities related to:

1. Performance of the preclosure safety analysis (PCSA), total system performance assessment (TSPA), and their inputs
2. Characterization related activities (i.e., acquisition, control, and analysis of samples and data), tests and experiments, and scientific studies that provide data to support PCSA, performance confirmation and total system performance assessment
3. Activities that are important to waste isolation and important to the safety functions of those SSCs (i.e., design, purchasing, fabricating, handling, packaging, shipping, storing, cleaning, erecting, installing, inspecting, testing, maintaining, repairing, and modifying SSCs).
4. Activities related to U. S. Department of Energy (DOE) high-level waste form from development through qualification, production, and acceptance.

Activities related to the characterization of DOE spent nuclear fuel, and its conditioning, treatment, and/or canisterization through acceptance.

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Attachment D

Criteria for Applying Quality Assurance Controls

Quality assurance controls must be applied to the degree (graded) commensurate with the:

- A. Function or end use of the item
- B. Consequence of failure (risk) of the item
- C. Importance of the data being collected or analyzed
- D. Complexity of design or fabrication of the item or design or implementation of the activity
- E. Reliability of the process
- F. Reproducibility of the results
- G. Uniqueness of the item or degree of standardization
- H. History of the item or service quality
- I. Necessity for special controls or processes
- J. Degree at which functional compliance can be demonstrated through inspection or test.